No. 10-972

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

After Eli Lilly and Company applied for a patent claiming the pharmaceutical composition gemcitabine, Lilly's scientists discovered a new use for it. Lilly applied for a second patent claiming the new use, and, on the same day, filed a continuation-in-part describing the new use and claiming priority to the original application. The Patent and Trademark Office granted Lilly two patents—the first for the composition and the second for its new use—but the Federal Circuit below declared the second patent invalid under the doctrine of double patenting because, as a result of the simultaneously filed but earlier-granted continuation-in-part application, the new use had been described in the first patent. The question presented is:

Whether the court of appeals erred by holding that the mere description of an invention in a patent renders a subsequently issued patent claiming that invention invalid.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*

Washington Legal Foundation ("WLF") is a non-profit public interest law and policy center that regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. WLF has participated in numerous court proceedings raising important issues regarding the patenting of pharmaceuticals and the enforcement of pharmaceutical patents. *See, e.g.*, *Allergan, Inc.* v. *Alcon Labs., Inc.*, 324 F.3d 1322, 1330 n.6 (Fed. Cir. 2003) (citing WLF's *amicus* brief); Br. of WLF as *Amicus Curiae* in Support of Eli Lilly and Company and Supporting En Banc Review, *Sun Pharm. Indus., Ltd.* v. *Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010) (No. 2010-1105).[1]

Correctly applied, the doctrine of double patenting "promote[s] the Progress of . . . useful Arts," U.S. Const. art. I, § 8, cl. 8, by ensuring that the monopoly granted to an invention persists only for a limited time. The decision below enlarges the doctrine in a manner that undermines the disclosure function of

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[1] Pursuant to this Court's Rule 37.2(a), *amicus* timely notified the parties of its intent to file this brief. The parties have consented to the filing of this brief in letters submitted herewith. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

patents, which, no less than the patent monopoly itself, is an engine of progress. WLF thus has a substantial interest in this Court's decision whether to grant review of the opinion below.

STATEMENT

In 1982, Dr. Larry Hertel, an employee of Eli Lilly and Company, invented a new and useful pharmaceutical composition called gemcitabine, the active ingredient in the drug Lilly now markets as Gemzar®. Pet. App. 2a, 57a, 59a-60a. Lilly filed an application to patent gemcitabine on March 10, 1983, describing the composition and a method of using it to treat viral infections. *Id.* at 3a, 60a.

While the application was still pending, Dr. Hertel and a collaborator at Lilly, Dr. Gerald Grindey, discovered a new use for gemcitabine—as a drug for treating cancer. *See* Pet. App. 4a, 61a-62a. Accordingly, Lilly filed an application for a second patent on December 4, 1984, claiming the new anticancer use. *Id.* at 4a. That same day, Lilly also filed a continuation-in-part of its original application, describing the anticancer use in a short paragraph. *See id.* at 3a-4a.

The Patent and Trademark Office ("PTO") subsequently granted Lilly two separate patents. The first, U.S. Patent No. 4,808,614 (the "'614 patent"), issued on February 28, 1989, and claimed Dr. Hertel's original invention: the composition gemcitabine and its antiviral use. Pet. App. 2a, 21a, 23a. The second, U.S. Patent No. 5,464,826 (the "'826 patent"), issued on November 7, 1995, and claimed Drs. Hertel and Grindey's subsequent discovery of gemcitabine's anticancer use. *Id.* at 2a, 23a-25a. The '614 patent expired on May 15, 2010, *id.* at 3a, and

the '826 patent is scheduled to expire on November 7, 2012, *id.* at 4a.

In 2007, Sun Pharmaceutical Industries, Ltd., a generic drug manufacturer, filed suit against Lilly in the U.S. District Court for the Eastern District of Michigan. Pet. App. 5a, 19a-20a. Seeking to market a generic version of Gemzar® for use as an anticancer medication before November 7, 2012, Sun requested a declaratory judgment that Lilly's '826 patent is invalid. *See id.* at 20a.

The district court declared the '826 patent invalid, Pet. App. 33a, and a three-judge panel of the Federal Circuit affirmed, *id.* at 2a. The panel rested its decision on the proposition that "a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Id.* at 12a (internal quotation marks omitted). That proposition, the panel held, "extends to any and all such uses disclosed in the specification of the earlier patent." *Ibid.* Thus, the panel concluded, although the '614 patent did not claim gemcitabine's anticancer use, the mere description of that use in the '614 patent renders the '826 patent invalid under the doctrine of double patenting. *See id.* at 18a. "In light of the earlier '614 patent's description of gemcitabine's use in treating cancer," the panel explained, "the asserted claims of the later '826 patent, which recite a method of using gemcitabine to treat cancer, are not patentably distinct from the '614 patent's claim to gemcitabine," because "[t]he asserted claims of the later '826 patent simply claim the anticancer use *disclosed* in the specification of the '614 patent." *Ibid.* (emphasis added).

By a five-to-four vote, the Federal Circuit denied Lilly's petition for rehearing en banc. *See* Pet. App. 131a-132a. Dissenting from that denial, Judge Newman, joined by Chief Judge Rader and Judges Lourie and Linn, argued that "[t]he law of double patenting is contrary to the panel's holding." *Id.* at 136a; *see also id.* at 138a ("The panel opinion violates a vast body of precedent."). The law of double patenting, Judge Newman explained, "is directed to whether the invention claimed in a later patent is an obvious variant of the invention claimed in an earlier patent"—*not* whether the invention claimed in a later patent happened to be described in an earlier one. *Id.* at 138a. After all, Judge Newman noted, "there is no dispute that Lilly would be entitled to a separate patent on the anticancer use if Lilly had not included the disclosure of anticancer use in the specification of the continuation-in-part filed the same day" as Lilly's '826 patent. *Id.* at 140a. Judge Newman therefore criticized the panel for failing to explain how its holding advanced the purpose of the doctrine of double patenting—a doctrine "intended to prevent *improper* timewise extension of the patent right." *Id.* at 139a-140a (internal quotation marks omitted).

SUMMARY OF ARGUMENT

It is a fundamental principle of patent law that an inventor is entitled to as many patents as he has inventions. The judicially created doctrine of double patenting is not supposed to disturb this principle. Instead, the doctrine is supposed to prevent an applicant from receiving *two* patents for *one* invention and thereby extending his monopoly on the single invention. Nevertheless, when Lilly obtained a patent for one invention (the pharmaceutical composition gemcitabine) and later obtained a second patent for a dis-

tinct invention (gemcitabine's subsequently discovered anticancer use), the Federal Circuit declared the second patent invalid for double patenting, thereby limiting Lilly to *one* patent for *two* inventions. The court of appeals rested its decision on a new inflexible and categorical rule—any description of an invention in an earlier-issued patent renders a later-issued patent claiming that invention invalid.

That rule conflicts not only with decisions of this Court, but also with decisions of the regional courts of appeals and longstanding rules of the PTO. What is more, the practical effect of Federal Circuit's decision to limit applicants to a single patent for two inventions will be to discourage disclosure and innovation, the twin pillars of a well-functioning patent system. Certiorari is warranted.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION BELOW CONFLICTS WITH DECISIONS OF THIS COURT, DECISIONS OF THE REGIONAL CIRCUITS, AND LONGSTANDING RULES OF THE PATENT AND TRADEMARK OFFICE.

A. THE DECISION BELOW CANNOT BE RECONCILED WITH THIS COURT'S DECISIONS.

In *Miller* v. *Eagle Manufacturing Co.*, 151 U.S. 186 (1894), which the decision below fails to cite, this Court affirmed "the well-settled rule that two valid patents for the same invention cannot be granted either to the same or to a different party." *Id.* at 197. Citing *Odiorne* v. *Amesbury Nail Factory*, 18 F. Cas. 578 (C.C.D. Mass. 1819) (No. 10,430) (Story, J.), the Court stated that the reason for the rule is to prevent what would otherwise amount to an improper

timewise extension of the term of a patent. *See Miller*, 151 U.S. at 198. Once a patent issues for an invention, the Court explained, "the power to create a monopoly is exhausted"; "a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." *Ibid.* Thus, the Court held, "[i]f, upon a proper construction of . . . two patents, . . . they should be considered as covering the same invention, then the later must be declared void" under the doctrine of double patenting. *Id.* at 196-97.

At the same time, the Court in *Miller* stressed that application of the doctrine of double patenting should not come at the expense of another fundamental principle of patent law—"that a later patent may be granted where the invention is clearly distinct from, and independent of, one previously patented." 151 U.S. at 199. The Court noted, for example, that "[a] single invention may include both the machine and the manufacture it creates, and in such cases, if the inventions are really separable, the inventor may be entitled to a monopoly of each." *Ibid.* By the same token, "an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent." *Ibid.*; *accord O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 122 (1854). Thus, while acknowledging that "no patent can issue for an invention actually covered by a former patent," the Court emphasized that "where the second patent covers matter described in the prior patent, essentially distinct and separable from the invention covered thereby and claims made thereunder, its validity may be sustained." *Miller*, 151 U.S. at 198.

The Federal Circuit's decision below—declaring Lilly's '826 patent invalid because the invention claimed therein was "*disclosed* in the specification of the '614 patent," Pet. App. 18a (emphasis added)—cannot be squared with *Miller*'s pronouncement that the validity of a second patent that "covers matter *described* in [a] prior patent . . . may be sustained" if the inventions at issue are "essentially distinct and separable," *Miller*, 151 U.S. at 198 (emphasis added). Here, there is no question that the initial discovery of a pharmaceutical composition and the subsequent discovery of a new use for that composition are separately patentable under the Patent Act. *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process . . . or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . ."); *id.* § 100(b) (defining the term "process" to include "a new use of a known . . . composition of matter"); *Ansonia Brass & Copper Co.* v. *Elec. Supply Co.*, 144 U.S. 11, 18 (1892) ("[I]f an old device or process be put to a new use which is not analogous to the old one, and the adaptation of such process to the new use is of such a character as to require the exercise of inventive skill to produce it, such new use will not be denied the merit of patentability."); 1 Donald S. Chisum, *Chisum on Patents* § 1.03[8][c] (2010) (confirming that courts "recognize the availability of process claims for new and nonobvious uses" of old inventions).

And yet, despite the fact that Lilly's '614 patent claimed only gemcitabine and its antiviral use, and the fact that the subsequent discovery of gemcitabine's anticancer use is separately patentable from both, the Federal Circuit declared the '826 patent invalid because the anticancer use claimed therein had been described in the '614 patent. Pet. App. 18a.

That holding contradicts this Court's decision in *Miller*, which makes plain that the mere description of an invention in an earlier-issued patent does not render a later-issued patent claiming that invention invalid. *See* 151 U.S. at 198; *accord* 3A Chisum, *supra*, § 9.01 ("[The doctrine of double patenting] does not preclude a second patent on subject matter that is disclosed but not claimed in the first patent."). The per se rule for which the decision below stands—that whenever a patent describes an invention, it renders a subsequent patent claiming that invention invalid—is inconsistent with the rule articulated in *Miller* that the validity of the subsequent patent "may be sustained," so long as the invention claimed therein is "essentially distinct and separable" from any invention previously patented. 151 U.S. at 198.

The decision below also conflicts with this Court's decision in *Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315 (1866), a case predating *Miller*. The plaintiff in *Suffolk* had sought to patent various improvements to a trunk used for cleaning cotton. The plaintiff's initial application claimed improvements to the interior arrangement of the trunk. *Id.* at 315. While that application was still pending, the plaintiff filed a second application, which claimed improvements to the trunk's form. *Id.* at 316. That application also described—but did not claim—the improvements covered by the plaintiff's initial application. *Ibid.* Thereafter, in March 1857, the plaintiff received a patent on his second application, for improvements to the trunk's form. *Ibid.* He then filed a third application, once again claiming improvements to the trunk's interior arrangement, which resulted in a patent in December 1857. *Ibid.* It was not until September 1860, nearly three years later, that the plaintiff finally received a patent on his ini-

tial application, also for improvements to the interior arrangement of the trunk. *Ibid.*

The plaintiff brought suit against the defendant for infringing the patent granted in December 1857 for improvements to the interior arrangement. *Suffolk*, 70 U.S. at 316-17. As a defense to infringement, the defendant argued a type of double patenting. *See id.* at 317. According to the defendant, the December 1857 patent was void because the failure of the prior March 1857 patent to claim improvements to the interior arrangement "operated as an abandonment or dedication of [those improvements] to the public." *Id.* at 318; *see also Fehr* v. *Activated Sludge, Inc.*, 84 F.2d 948, 953 (7th Cir. 1936) (describing as a type of double patenting the situation that arises "where the inventor claims one form of his invention in one patent, and at a later time claims another form which was disclosed in his earlier application," but only "where there has been such a delay as to amount to a dedication").

This Court disagreed. It held that the pendency of the plaintiff's initial application, for the "same" improvements to the interior arrangement of the trunk, "repelled any inference of abandonment or dedication from the omission to again claim [them]" in the March 1857 patent. *Suffolk*, 70 U.S. at 318. Thus, despite the fact that improvements to the interior arrangement had been previously described in the March 1857 patent, the Court "d[id] not perceive any objection" to the process resulting in the December 1857 patent actually claiming those improvements. *Id.* at 319.

This Court's decision in *Suffolk* cannot be reconciled with the Federal Circuit's decision below. In rejecting the defendant's double-patenting argument,

this Court perceived *no* objection to the validity of the plaintiff's second patent, *even though* his first patent had already described the same invention. *Suffolk*, 70 U.S. at 319. But the Federal Circuit below *did* object to the validity of Lilly's second patent, *precisely because* Lilly's first patent had already described gemcitabine's anticancer use. Pet. App. 18a. The holding below flatly contradicts the decision in *Suffolk*.

This Court should grant certiorari to resolve the conflict between the Federal Circuit's decision below and this Court's decisions in *Miller* and *Suffolk*. Without this Court's intervention, a rule contrary to the principles articulated in this Court's cases will continue to distort the patent law of this Nation.

B. The Decision Below Conflicts With Decisions Of The Regional Courts Of Appeals.

"Not all cases involving a patent-law claim fall within the Federal Circuit's jurisdiction." *Holmes Group, Inc.* v. *Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 834 (2002). To be sure, the Federal Circuit has exclusive appellate jurisdiction over all actions arising under federal patent law. *See* 28 U.S.C. §§ 1295(a)(1), 1338(a). But the regional circuits continue to have appellate jurisdiction over actions in which patent-law issues are presented only in the defendant's answer. *See Holmes*, 535 U.S. at 830-32. Because the doctrine of double patenting could be raised as a counterclaim in an action outside the Federal Circuit's exclusive jurisdiction, a conflict with the regional circuits over the question presented would furnish a compelling reason for this Court to grant certiorari. *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998) (citing the conflict between the

Federal Circuit's decision and the decisions of regional circuits as a reason for granting certiorari); *see also Holmes*, 535 U.S. at 839 (Stevens, J., concurring in part and concurring in the judgment) (noting that a conflict between the Federal Circuit and the regional circuits "may be useful in identifying questions that merit this Court's attention," and that "occasional decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias").

Such a conflict is present here. Each of the regional courts of appeals to have addressed the question presented has rejected the Federal Circuit's per se rule that a patent is invalid whenever the invention claimed therein was described in an earlier-issued patent. In accordance with this Court's decisions in *Miller* and *Suffolk*, these other circuits have recognized that the mere description of an invention in an earlier-issued patent does not render a later-issued patent claiming that invention invalid.

In *Century Electric Co. v. Westinghouse Electric & Manufacturing Co.*, 191 F. 350 (8th Cir. 1911), for example, the Eighth Circuit, in an opinion authored by Judge Walter Sanborn and joined by then-Judge Van Devanter, affirmed that:

> one who makes several patentable inventions that result in a new and useful machine or process, or both, may have as many separate valid patents as he makes patentable inventions. His is the option to secure all these inventions by a single patent, or by many patents, and the fact that he describes all of them in his application or specification for an earlier patent to secure one or more of

> them, *does not invalidate a subsequent patent to him for those inventions there described but not claimed.*

Id. at 353 (emphasis added).

At issue in *Century Electric* were three inventions of Nikola Tesla. In 1888, Tesla had applied for two patents: one for a method of using a motor, and the other for the motor itself. *Id.* at 352-54. In 1889, while his first two applications were still pending, Tesla had filed a third application, for an improved motor. *Id.* at 353-54. His third application described—but did not claim—the method and motor that formed the basis of his first two applications. *Id.* at 357. And though it was the last of his applications filed, his third was the first granted by the Patent Office in 1891. *Id.* at 352. A patent for the method did not issue until 1894, and a patent for the original motor, not until 1896. *Ibid.* As a defense to infringement of Tesla's patents, the defendant argued that the latter two patents were invalid for double patenting over the 1891 patent, which had described the method and the motor claimed by the latter two. *Ibid.* Rejecting this argument, the Eighth Circuit explained that the defendant had "fail[ed] to give due weight" to the rule that an inventor "may *describe* in an application an invention which he does not *claim* therein without waiving his right to claim and secure a subsequent patent for it." *Id.* at 358 (emphases added).

The Sixth Circuit applied the same rule in *Thomson-Houston Electric Co.* v. *Ohio Brass Co.*, 80 F. 712 (6th Cir. 1897) (Taft, J.). That case involved two patent applications relevant here: the first, filed in 1887, for improvements in suspended switches for electric railways, *id.* at 713, 715; the second, filed a

year later, for improvements relating to those claimed in the first application, *id.* at 717-18. The patent resulting from the second application, which was granted in 1889, described (but did not claim) the improvements covered by the first application, which was not granted until the following year. *See id.* at 713, 717, 724. Sued for infringement, the defendant claimed that the later-issued patent was invalid for double patenting over the earlier-issued patent. *Id.* at 714, 724. In an opinion by then-Judge Taft, the Sixth Circuit quoted the passage in *Miller* stating that "'where the second patent covers matters described in the prior patent, essentially distinct and separable from the invention covered thereby and claims made thereunder, its validity may be sustained.'" *Id.* at 728 (quoting *Miller*, 151 U.S. at 198). The court of appeals then rejected the defendant's double-patenting argument as contrary to *Miller*, and held that the later-issued patent was "not rendered void by" the earlier-issued patent. *Ibid.*

When the same question of double patenting arose in a case involving the same patents, the Second Circuit reached the same conclusion: The patent issued later was valid, despite the fact that its claimed invention had been described in the patent issued earlier. *See Thomson-Houston Elec. Co.* v. *Elmira & H. Ry. Co.*, 71 F. 396, 407 (2d Cir. 1896). Decades later, the Second Circuit expounded the same principle in *Traitel Marble Co.* v. *U.T. Hungerford Brass & Copper Co.*, 22 F.2d 259 (2d Cir. 1927), a case involving a patent for an apparatus and a subsequent patent for improvements to it. Writing for the Second Circuit in *Traitel*, Judge Learned Hand stated that "it is never an objection to an improvement patent that an earlier generic patent has covered the same structure, and each is valid, though

taken out by a single inventor." *Id.* at 262. He then concluded that the patents before him presented "precisely the same situation, except that, because the applications were copending, it is not necessary that the improvement should be an invention over the matters *disclosed* in the other application." *Ibid.* (emphasis added). Judge Hand's opinion has been properly understood to mean that "the claim of the second application need not be a patentable advance over the *disclosures of the specifications* (as distinct from the claims) of the first application." *S.H. Kress & Co.* v. *Aghnides*, 246 F.2d 718, 726 (4th Cir. 1957) (per curiam on motions for rehearing).

The Fourth Circuit's decision in *Montgomery Ward & Co.* v. *Gibbs*, 27 F.2d 466 (4th Cir. 1928), stands for the identical proposition. The plaintiff there brought suit alleging infringement of a patent claiming "improvements in traps designed for the capture of fur-bearing animals." *Id.* at 467. The defendant contended that the patent in suit was void for double patenting over a previously issued patent, *id.* at 468, but the Fourth Circuit disagreed. The court of appeals found that the "two patents . . . were copending, and while a somewhat similar trap was described in [the earlier-issued patent], it was not there claimed as in [the patent in suit], although described." *Ibid.* Recognizing that "[i]t is not fatal if the invention of the second patent is *disclosed* in the earlier patent, provided it is not *claimed* there, and the applications for the two patents were copending," the Fourth Circuit concluded that the defendant's claim of double patenting was "not well founded." *Id.* at 469 (emphases added).

Reiterating the same principle in a later case, the Fourth Circuit stated that "where the applicant

files a second application while the earlier one is still pending in the Patent Office, and the first patent contains *disclosures not embodied in the claims*, he is not barred from embodying the unclaimed disclosures in the later application." *Aghnides*, 246 F.2d at 726 (emphasis added). Agreeing with the Fourth Circuit's approach, the Ninth Circuit has quoted that passage directly in an opinion of its own. *Intricate Metal Prods., Inc.* v. *Schneider*, 324 F.2d 555, 560 (9th Cir. 1963). The Seventh Circuit has made clear that it, too, recognizes the same principle. In setting forth the "correct" test for double patenting in *Weatherhead Co.* v. *Drillmaster Supply Co.*, 227 F.2d 98 (7th Cir. 1955), the Seventh Circuit declared that "[w]hen determining whether or not double patenting exists only the claims are compared." *Id.* at 102. Accordingly, the Seventh Circuit explained, "when [copending] applications were made by the same inventor and the doctrine of double patenting applies, the later patent need not show an inventive advance over what was *disclosed* but not *claimed* in the earlier patent." *Ibid.* (emphases added).

In addition to the circuits discussed above, three other regional courts of appeals in considering double-patenting defenses have quoted the key passage in *Miller*, 151 U.S. at 198, in which this Court stated: "[W]here the second patent covers matter described in the prior patent, essentially distinct and separable from the invention covered thereby and claims made thereunder, its validity may be sustained." *Am. Commc'ns Co.* v. *Pierce*, 208 F.2d 763, 766 (1st Cir. 1953); *Wahl* v. *Rexnord, Inc.*, 624 F.2d 1169, 1178 (3d Cir. 1980); *Pierce* v. *Allen B. Du Mont Labs., Inc.*, 297 F.2d 323, 327 (3d Cir. 1961); *Smith* v. *Kingsland*, 178 F.2d 26, 30 (D.C. Cir. 1949). Unlike the Federal Circuit below, which did not cite *Miller*, these other cir-

cuits recognize that the validity of a patent "may be sustained," even if the invention claimed therein was described previously in an earlier-issued patent.

As the foregoing demonstrates, the Federal Circuit's decision below conflicts with the decisions of every regional circuit to have addressed the question presented. Following this Court's decisions in *Miller* and *Suffolk*, the First, Second, Third, Fourth, Sixth, Seventh, Eighth, Ninth, and D.C. Circuits have made clear that the mere description of an invention in a patent does not render a subsequently issued patent claiming that invention invalid. The Federal Circuit's adoption of a directly contrary rule warrants this Court's review.

C. The Decision Below Contradicts Longstanding Rules Of The Patent And Trademark Office.

In addition to contradicting the decisions of this Court and the regional courts of appeals, the Federal Circuit's decision below conflicts with longstanding rules of the PTO.

At the time the two applications at issue here were filed, the PTO's rules barred an applicant from presenting, in a single application, claims to a composition and more than one method of using that composition. *See* 37 C.F.R. § 1.141(a)-(b) (1984). The rules thus required Lilly to present its claims to gemcitabine and its antiviral use in one application, and its claim to gemcitabine's anticancer use in another—which is precisely what Lilly did. If Lilly had violated these rules by presenting its claims in only a single application, the PTO would have simply forced Lilly's claims into separate patents by restricting the

application's scope. *See* 35 U.S.C. § 121; 37 C.F.R. § 1.142(a).

Similarly, today, the PTO's rules provide that "[t]wo or more independent and distinct inventions may not be claimed in one national application." 37 C.F.R. § 1.141(a) (2011). And the Manual of Patent Examining Procedure makes clear that gemcitabine's anticancer use would be regarded as an invention independent and distinct from gemcitabine and its antiviral use. *See* U.S. PTO, Manual of Patent Examining Procedure § 806.05(h) (8th ed. rev. 5 2006) ("A product and a process of using the product can be shown to be distinct inventions if . . . the product as claimed can be used in a materially different process."). Thus, presented with Lilly's claims today, the PTO would still require that they be divided into two separate applications, through imposing a restriction requirement if necessary. *See* 35 U.S.C. § 121.

The Federal Circuit's decision effectively nullifies the PTO's longstanding policy of prohibiting claims like Lilly's from being claimed in a single application. In declaring Lilly's '826 patent invalid for double patenting, the court of appeals concluded that Lilly's claim to gemcitabine's anticancer use is "not patentably distinct from the '614 patent's claim to gemcitabine." Pet. App. 18a. That conclusion directly conflicts with the PTO's rules, which required that Lilly obtain two distinct patents for its claims to gemcitabine and its anticancer use. The decision below will thus have the effect of binding claims together through the doctrine of double patenting that the PTO has long required to be patented separately under its own rules. Because the decision below essentially negates the policies of the PTO, this Court

should not deny the petition without at least first calling for the views of the Solicitor General.

II. Proper Application Of The Doctrine Of Double Patenting Is A Matter Of Special Importance Warranting This Court's Review.

As noted above, the Federal Circuit has exclusive appellate jurisdiction over all actions arising under federal patent law. *See* 28 U.S.C. §§ 1295(a)(1), 1338(a). That alone makes "the rule that it applied in this case . . . a matter of special importance to the entire Nation." *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993). But even beyond that, the decision below is of special importance because its expansion of the judicially created doctrine of double patenting threatens to undermine the constitutionally defined purposes of our Nation's patent system.

Article I of the Constitution empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. A patent gives an inventor "the exclusive right to practice [an] invention for a period of years." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). But the granting of such rights is only a means to "promot[ing] the Progress of . . . useful Arts." "[T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure." *Ibid.*

The Federal Circuit's decision below seriously undermines this goal. By giving preclusive effect to disclosures of new inventions in an previously issued

patent, the Federal Circuit's decision discourages inventors from making such disclosures in the first place. As the four judges who dissented from the denial of rehearing below noted, "there is no dispute that Lilly would be entitled to a separate patent on the anticancer use if Lilly had not included the disclosure of anticancer use in the specification of the continuation-in-part filed the same day" as Lilly's '826 patent application. Pet. App. 140a. By limiting Lilly to one patent for two inventions, the decision below effectively penalizes Lilly for having described the anticancer use in a copending application. The lesson for future patent applicants is simple: Always disclose as little as possible.

That lesson rings especially true given that inventors seeking to patent more than one invention can never be sure about the order in which the PTO will grant their applications. Not infrequently, an inventor files an application for an invention followed later by an application for improvements in that invention, while the original application is still pending. In many cases, "the course of an application for a generic or broad invention may legitimately take longer in its course through the patent office than a comparatively unimportant improvement on that invention." *Ohio Brass*, 80 F. at 727 (Taft, J.). As a result, the PTO grants the applications out of order: The application for the improvements issues first, and the application for the basic invention issues second. *See, e.g.*, *Suffolk*, 70 U.S. at 315-16 (involving similar facts); *Century Elec.*, 191 F. at 352 (same); *Ohio Brass*, 80 F. at 713, 717 (same).

Under the Federal Circuit's per se rule, the later-issued patent for the basic invention will be declared

invalid for double patenting because the earlier-issued patent will invariably describe the basic invention in the course of claiming improvements in it. The inventor will thus be limited to one patent for two inventions simply because the PTO granted his applications out of order; had the PTO instead granted his applications in the order in which they were filed, the inventor would have received two patents—one for each of his distinct inventions. The Federal Circuit has therefore decided that in circumstances involving copending applications, the number of valid patents to which an inventor is entitled will depend on the most arbitrary of factors: which application the PTO grants first.

Seeking to avoid the risk of having patents for their basic inventions declared invalid, inventors will simply seek to patent their inventions one at a time, thereby delaying "the Progress of . . . useful Arts." Rather than seek to patent improvements in their basic inventions while their original applications for those inventions are still pending, inventors will delay filing any improvement applications until their original applications are granted, out of fear that the mere description of the basic invention in a copending improvement application could result in an earlier-issued patent giving rise to double patenting. In some cases, inventors may decide never to reveal their later-discovered improvements. The practical effect of the decision below will thus be to discourage inventors from promptly filing applications to patent new inventions and discoveries. This delay in disclosure will, in turn, harm innovation overall. For not only will inventors be unwilling to practice their new inventions while other of their applications are still pending before the PTO, but they will be unable to learn from, and

improve upon, the inventions of others that would have otherwise been disclosed in the absence of the Federal Circuit's rule.[2]

The per se rule announced by the decision below—that whenever a patent describes an invention, it renders a later-issued patent claiming that invention invalid—will serve only to undermine disclosure and innovation, the touchstones of a well-functioning patent system. As this Court has noted, the adoption of "categorical rules" carries the danger of "wide-ranging and unforeseen impacts." *Bilski* v. *Kappos*, 130 S. Ct. 3218, 3229 (2010); *see also KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 415 (2007) ("rejecting the rigid approach" of the Federal Circuit to the question of obviousness under 35 U.S.C. § 103); *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (holding that the Federal Circuit "erred in its categorical grant" of permanent injunctive relief). But that danger may be at its zenith where, as here, the categorical rule threatens the careful balance of competing interests secured by a judicially created

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[2] Although the terms of patents resulting from applications filed today are measured from their application filing dates rather than from their patent issue dates, *see* Uruguay Round Agreements Act, Pub. L. No. 103-465, sec. 532, § 154(a)(2), 108 Stat. 4809, 4984 (1994) (codified at 35 U.S.C. § 154(a)(2)), the decision below will still have the effect of causing inventors to seek to patent their inventions one at a time. Because the terms of patents for basic inventions are frequently increased, *see* 35 U.S.C. §§ 154(b), 156, inventors will still be discouraged from filing copending applications for new improvements, given the risk under the Federal Circuit's rule that a shorter-termed patent for new improvements will render a longer-termed patent for the basic invention invalid. *See In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009).

doctrine. *See Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738-39 (2002) (rejecting, in favor of a "flexible bar," the Federal Circuit's adoption of a "complete bar" when considering what claims of equivalence are estopped by prosecution history). That the Federal Circuit's decision so seriously undermines "the Progress of . . . useful Arts" is reason enough for this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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